

CLAIMS

1. (withdrawn) A composition comprising one or more pellets for a timed or retarded release of a water-soluble nutritional supplement in the stomach and/or gastrointestinal tract of a human, wherein said one or more pellets comprise: an admixture of an effective amount of a nutritional supplement to be released at a controlled rate and a formulation comprising the components (1) a saccharide, (2) an excipient, (3) a lubricant, (4) an agglutinative, (5) a stabilizing agent and (6) a plasticizer wherein, (1) said water-soluble nutritional supplement is present in an amount of about 60% to about 95% by weight; (2) said saccharide is present in an amount of about 1.5% to about 15% by weight; (3) said excipient is present in an amount of about 0.6% to about 6% by weight; (4) said lubricant is present in an amount of about 0.07% to about 1% by weight; (5) said agglutinative is present in an amount of about 0.3% to about 3% by weight; (6) said stabilizing agent is present in an amount of about 1% to about 10% by weight; and (7) said plasticizer is present in an amount of about 0.1% to about 1% by weight.

2. (withdrawn) The composition according to claim 1 wherein: (1) said water-soluble nutritional supplement is present in an amount of about 75% to about 95% by weight; (1) said saccharide is present in an amount of about 3% to about 8% by weight; (2) said excipient is present in an amount of about 1% to about 3% by weight; (3) said lubricant is present in an amount of about 0.15% to about 0.5% by weight; (4) said agglutinative is present in an amount of about 0.6% to about 1.5% by weight; (5) said stabilizing agent is present in an amount of about 2% to about 5% by weight; and (6) said plasticizer is present in an amount of about 0.2% to about 0.5% by weight.

3. (withdrawn) The composition according to claim 2 wherein: (1) said water-soluble nutritional supplement is present in an amount of about 88% by weight; (2) said saccharide is present in an amount of about 5% by weight; (3) said excipient is present in an amount of about 1.8% by weight; (4) said lubricant is present in an amount of about 0.22% by weight; (5) said agglutinative is present in an amount of about 1.0% by weight; (6) said stabilizing agent is present in an amount of about 3.66% by weight; and (7) said plasticizer is present in an amount of about 0.35% by weight.

4. (withdrawn) The composition according to claim 3 wherein said pellet(s) of said composition are inside a hard capsule.

5. (withdrawn) The composition according to claim 1 wherein said water-soluble nutritional supplement is derived from a leaf, a root, or extract of a plant selected from one or more of the group consisting of: artichoke, bilberry, bioflavonoid, boswellia, bupleurium, chamomile, chlorophyll, cranberry, damiana, echinacea, essiac, garcinia cambogia, garlic, germanium, ginger, ginkgo, ginseng, goldenseal, grape seed, green tea, hawthorne berry, hesperidin, hops, horse chestnut, hydrangea, hypericum, indole-3-carbinol, licorice, lycopene, nettle root, peppermint, periwinkle, policosanol, psyllium, pygeum, quercetin, raspberry, resveratol, rutin, sassafras, saw palmetto, silymarin, tribulus terrestris, turmeric, valerian, and wild yam or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

6. (withdrawn) The composition according to claim 5 wherein said water-soluble nutritional supplement is selected from one or more of the group consisting of acetyl-L-carnosine, alpha lipoic acid, amylase, androstendiol, androstendione, arginine, ascorbic acid, B vitamin, beta-carotene, biotin, bromelain, calcium,

chicken collagen, chitosan, choline, chondroitin, coenzyme Q10, creatine, dehydroepiandrosterone, diethylmethlaminoethanol, dihydroepiandsterone, dimethylglycine, DMSO, gammahydroxybutric acid (GABA), glucosamine, glutamine, glutathione, hyaluronic acid, hydroxytryptophan, indium, isoleucine, 1-carnitine, lactoferrin, lecithin, leucine, lipase, lumbrokinase, lutein, magnesium, melatonin, Methylcobalamin, methylsulfonylmethane, MGN 3, ornithine, pancreatin, panthethoic acid, papain, para-amino benzoic acid (PABA), phenylalanine, phosphatidylcholine, phosphatidylserine, potassium, pregnenalone, protease, retinoic acid, retinol, s-adenosyl-methionine, selenium, taurine, theanine, thymase, tocopherol, trimethylglycine, tryptophan, tyrosine, valine, vinpocetine, vitamin D, vitamin A, zeathanthine, and zinc, or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

7. (withdrawn) The composition according to claim 6 wherein said water-soluble nutritional supplement comprises glucosamine sulfate, or nutraceutically acceptable salt, ether, ester, acid or derivative thereof.

8. (withdrawn) The composition according to claim 6 wherein said water-soluble nutritional supplement comprises chondroitin, or

nutraceutically acceptable salt, ether, ester, acid or derivative thereof.

9. (withdrawn) The composition according to claim 1 wherein said saccharide comprises refined sugar.

10. (withdrawn) The composition according to claim 9 wherein said refined sugar is selected from one or more of the group consisting of beet sugar, brown sugar, cane sugar, caramel, caramelized sugar, corn sugar, granulated sugar, and fructose.

11. (withdrawn) The composition according to claim 1 wherein said saccharide comprises monosaccharides and disaccharides.

12. (withdrawn) The composition according to claim 11 wherein said monosaccharides and said disaccharides are selected from one or more of the group consisting of galactose, lactose, trehalose, sucrose, glucose, mannose, maltose, ribose, xylose and arabinose.

13. (withdrawn) The composition according to claim 1 wherein said excipient is selected from one or more of the group consisting of silicon dioxide, microcrystalline cellulose,

calcium phosphate, calcium sulfate, sodium lauryl sulfate, silicified microcrystalline cellulose and silicon dioxide.

14. (withdrawn) The composition according to claim 13 wherein said excipient comprises silicon dioxide.

15. (withdrawn) The composition according to claim 1 wherein said lubricant is selected from one or more of the group consisting of magnesium stearate, stearic acid, and talc.

16. (withdrawn) The composition according to claim 15, wherein said lubricant comprises talc.

17. (withdrawn) The composition according to claim 1 wherein said agglutinative is selected from one of more of the group consisting of polyacrylates, polymethacrylates, polyvinylpyrrolidone, poly(vinyl acetate), various starches, corn products such as amaizo, amylose and zein, pectin, alkoxylated celluloses, polyesters, polyethers, polyethylene glycol, proteins, nucleic acids, albumin, gelatin, starch, collagen, dextran and modified dextrans, polysaccharides, polylactide/polyglycolide, polyalkylcyanoacrylates, polyacrylamide, polysorbates, polyethylene ethers, polyethylene

esters, polyoxyethylene/polyoxypropylene block polymerss, cellulose acetophthalate, hydroxypropylmethyl cellulose phthalate, cellulose esters, cellulose diesters, cellulose triesters, cellulose ethers, cellulose ester-ether, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate propionate, cellulose acetate butyrate, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, propyl cellulose, hydroxypropyl cellulose, lower-substituted hydroxypropyl cellulose, carboxymethyl cellulose, and hydroxypropylmethyl cellulose.

18. (withdrawn) The composition according to claim 17 wherein said agglutinative comprises hydroxypropylmethyl cellulose.

19. (withdrawn) The composition according to claim 1 wherein said stabilizing agent is selected from one or more of the group consisting of shellac and constituent aliphatic polyhydroxy acids of shellac, ascorbic acid, benzoic acid and fumaric acid.

20. (withdrawn) The composition according to claim 19 wherein said stabilizing agent comprises Shellac gum.

21. (withdrawn) The composition according to claim 1 wherein said plasticizer is selected from one or more of the group consisting of, adipate, azelate, enzoate, citrate, stearate, isoebucate, sebacate, triethyl citrate, tri-n-butyl citrate, acetyl tri-n-butyl citrate, citric acid esters, triacetin, acetylated monoglyceride, grape seed oil, olive oil, sesame oil, acetyltributylcitrate, acetyltriethylcitrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethylfumarate, dibutylsuccinate, diethylmalonate, dioctylphthalate, dibutylsebacate, triethylcitrate, tributylcitrate, glyceroltributyrate and diethylphthalate.

22. (withdrawn) The composition according to claim 21 wherein said plasticizer comprises diethylphthalate.

23. (previously presented) A composition comprising one or more pellets for a timed or retarded release of a water-soluble nutritional supplement in the stomach and/or gastrointestinal tract of a human, wherein said one or more pellets comprise: an admixture of an effective amount of a nutritional supplement to be released at a controlled rate and a formulation comprising the components (1) a saccharide, (2) an excipient, (3) a

lubricant, (4) an agglutinative, and (5) a plasticizer wherein, (1) said water-soluble nutritional supplement is present in an amount of about 60% to about 95% by weight; (2) said saccharide is present in an amount of about 1.5% to about 15% by weight; (3) said excipient is present in an amount of about 0.6% to about 6% by weight; (4) said lubricant is present in an amount of about 0.3% to about 3% by weight; (5) said agglutinative is present in an amount of about 0.3% to about 3% by weight; (6) said plasticizer is present in an amount of about 1.5% to about 12% by weight.

24. (original) The composition according to claim 23 wherein: (1) said water-soluble nutritional supplement is present in an amount of about 75% to about 95% by weight; (2) said saccharide is present in an amount of about 3% to about 8% by weight; (3) said excipient is present in an amount of about 1% to about 3% by weight; (4) said lubricant is present in an amount of about 0.15% to about 0.5% by weight; (5) said agglutinative is present in an amount of about 0.6% to about 1.5% by weight; (6) said plasticizer is present in an amount of about 2% to about 6% by weight.

25. (original) The composition according to claim 24 wherein:

(1) said water-soluble nutritional supplement is present in an amount of about 88% by weight; (2) said saccharide is present in an amount of about 5% by weight; (3) said excipient is present in an amount of about 1.8% by weight; (4) said lubricant is present in an amount of about 0.22% by weight; (5) said agglutinative is present in an amount of about 1.0% by weight; (6) said plasticizer is present in an amount of about 4% by weight.

26. (withdrawn) A composition comprising one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement, wherein said pellets comprise: a core comprising: about 62% to about 99% by weight of a water-soluble nutritional supplement; about 1.5% to about 16% by weight of a saccharide; about 0.65% to about 6.5% by weight of an excipient; about 0.05% to about 0.5% of a lubricant; about 0.3% to about 3% by weight of an agglutinative; and a semipermeable coating surrounding the core comprising: about 20% to about 80% by weight of a lubricant; about 25% to about 90% by weight of a stabilizing agent; about 1.5% to about 15% by weight of a plasticizer.

27. (currently amended) The composition according to claim 23 wherein: said ~~eore~~ pellet comprises: about 78% to about 99% by weight of said water-soluble nutritional supplement; about 3% to about 8.3% by weight of said saccharide; about 1% to about 3.3% by weight of said excipient; about 0.05% to about 0.5% by weight of said lubricant; about 0.6% to about 1.6% by weight of said agglutinative; and ~~said~~ a semipermeable coating surrounding said ~~eore~~ pellet comprises: about 30% to about 50% by weight of said lubricant; about 40% to about 60% by weight of said stabilizing agent; about 3% to about 10% of said plasticizer.

28. (currently amended) The composition according to claim 27 wherein: said ~~eore~~ pellet comprises: about 92% by weight of said water-soluble nutritional supplement; about 5% by weight of said saccharide; about 2% by weight of said excipient; about 0.1% by weight of said lubricant; about 1% by weight of said agglutinative; and ~~said~~ a semipermeable coating surrounding said ~~eore~~ pellet comprises: about 42% by weight of said lubricant; about 53% by weight of said stabilizing agent; about 5% by weight of said plasticizer.

29. (previously presented) The composition according to claim 23 wherein one or more of said pellet(s) are inside of a gel

capsule.

30. (withdrawn) The composition according to claim 26 wherein said water-soluble nutritional supplement is derived from a leaf, root, or extract of a plant selected from the group consisting of artichoke, bilberry, bioflavonoid, boswella, bupleurium, chamomile, chlorophyll, cranberry, damiana, echinacea, essiac, garcinia cambogia, garlic, germanium, ginger, ginkgo, ginseng, goldenseal, grape seed, green tea, hawthorne berry, hesperidin, hops, horse chestnut, hydrangea, hypericum, indole-3-carbinol, licorice, lycopene, nettle root, peppermint, periwinkle, policosanol, psyllium, pygeum, quercetin, raspberry, resveratrol, rutin, sassafras, saw palmetto, silymarin, tribulus terrestris, turmeric, valerian, and wild yam; or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

31. (previously presented) The composition according to claim 23 wherein said water-soluble nutritional supplement is selected from one or more of the group consisting of acetyl-L-carnosine, alpha lipoic acid, amylase, androstendiol, androstendione, arginine, ascorbic acid, B vitamin, beta-carotene, biotin, bromelain, calcium, chicken collagen, chitosan, choline,

chondroitin, coenzyme Q10, creatine, dehydroepiandrosterone, diethylmethylaminoethanol, dihydroepiandrosterone, dimethylglycine, DMSO, gammahydroxybutric acid (GABA), glucosamine, glutamine, glutathione, hyaluronic acid, hydroxytryptophan, indium, isoleucine, 1-carnitine, lactoferrin, lecithin, leucine, lipase, lumbrokinase, lutein, magnesium, melatonin, Methylcobalamin, methylsulfonylmethane, MGN 3, ornithine, pancreatin, panthethoic acid, papain, para-amino benzoic acid (PABA), phenylalanine, phosphatidylcholine, phosphatidylserine, potassium, pregnenalone, protease, retinoic acid, retinol, s-adenosyl-methionine, selenium, taurine, theanine, thymase, tocopherol, trimethylglycine, tryptophan, tyrosine, valine, vinpocetine, vitamin D, vitamin A, zeathanthine, and zinc.; or a nutraceutically acceptable salt, ether, ester, acid, or derivative thereof.

32. (previously presented) The composition according to claim 23 wherein said saccharide comprises refined sugar.

33. (original) The composition according to claim 32 wherein said refined sugar is selected from one or more of the group consisting of beet sugar, brown sugar, cane sugar, caramel, caramelized sugar, corn sugar, granulated sugar, and fructose.

34. (previously presented) The composition according to claim 23 wherein said saccharide comprises monosaccharides and disaccharides.

35. (original) The composition according to claim 34 wherein said monosaccharides and said disaccharides are selected from one or more of the group consisting of galactose, lactose, trehalose, sucrose, glucose, mannose, maltose, ribose, xylose and arabinose.

36. (previously presented) The composition according to claim 23 wherein said excipient is selected from one or more of the group consisting of silicon dioxide, microcrystalline cellulose, calcium phosphate, calcium sulfate, sodium lauryl sulfate, silicified microcrystalline cellulose and silicon dioxide.

37. (original) The composition according to claim 36 wherein said excipient comprises silicon dioxide.

38. (previously presented) The composition according to claim 23 wherein said lubricant is selected from the group consisting of magnesium stearate, stearic acid, and talc.

39. (original) The composition according to claim 38 wherein said lubricant comprises talc.

40. (previously presented) The composition according to claim 23 wherein said agglutinative is selected from one or more of the group consisting of polyacrylates, polymethacrylates, polyvinylpyrrolidone, poly(vinyl acetate), various starches, corn products such as amazo, amylose and zein, pectin, alkoxylated celluloses, polyesters, polyethers, polyethylene glycol, proteins, nucleic acids, albumin, gelatin, starch, collagen, dextran and modified dextrans, polysaccharides, polylactide/polyglycolide, polyalkylcyanoacrylates, polyacrylamide, polysorbates, polyethylene ethers and esters, and polyoxyethylene/polyoxypropylene block polymers, cellulose acetophthalate, hydroxypropylmethyl cellulose phthalate, cellulose esters, cellulose diesters, cellulose triesters, cellulose ethers, cellulose ester-ether, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate propionate, cellulose acetate butyrate, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, propyl cellulose, hydroxypropyl cellulose, lower-substituted hydroxypropyl

cellulose, carboxymethyl cellulose, and hydroxypropylmethyl cellulose.

41. (original) The composition according to claim 40 wherein said agglutinative comprises hydroxypropylmethylcellulose.

42. (previously presented) The composition according to claim 23 wherein said stabilizing agent is selected from the group consisting of shellac and its constituent aliphatic polyhydroxy acids, ascorbic acid, benzoic acid and fumaric acid.

43. (original) The composition according to claim 42 wherein said stabilizing agent comprises Shellac gum.

44. (previously presented) The composition according to claim 23 wherein said plasticizer is selected from one or more of the group consisting of, adipate, azelate, enzoate, citrate, stearate, isoebucate, sebacate, triethyl citrate, tri-n-butyl citrate, acetyl tri-n-butyl citrate, citric acid esters, triacetin, acetylated monoglyceride, grape seed oil, olive oil, sesame oil, acetyltributylcitrate, acetyltriethylcitrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethylfumarate, dibutylsuccinate, diethylmalonate,

dioctylphthalate, dibutylsebacate, triethylcitrate, tributylcitrate, glyceroltributyrate and diethylphthalate.

45. (original) The composition according to claim 44 wherein said plasticizer comprises diethylphthalate.

46. (withdrawn) A composition comprising one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement, wherein said pellets comprise: a core comprising: about 92% by weight of said water-soluble nutritional supplement; about 5% by weight of said saccharide; about 2% by weight of said excipient; about 0.1% by weight of said lubricant; about 1% by weight of said agglutinative; and said semipermeable coating surrounding said core comprises: about 97% by weight of said plasticizer; about 2.25% by weight of said lubricant;

47. (previously presented) The composition according to claim 31 wherein said water-soluble nutritional supplement comprises chondroitin.

48. (cancelled) The composition according to claim 23 wherein the timed or retarded release dosage release pellet exhibits the

following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hour about 10% to about 30% of said nutritional supplement is released; after 4 hours about 50% to about 75% of said nutritional supplement is released; and after 8 hours about 75% to about 95% of said nutritional supplement is released; after 12 hours about 80% to about 100% of said nutrition supplement is released.

49. (withdrawn) The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hour about 19% of said nutritional supplement is released; after 4 hours about 59% of said nutritional supplement is released; after 8 hours about 81% of said nutritional supplement is released; and after 12 hours about 88% of said nutritional supplement is released.

50. (withdrawn) The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1

hour about 15% to about 35% of said nutritional supplement is released; after 4 hours about 45% to about 75% of said nutritional supplement is released; and after 8 hours about 75% to about 95% of said nutritional supplement is released; after 12 hours about 80% to about 100% of said nutritional supplement is released.

51. (previously presented) The composition according to claim 23 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hour about 30% of said nutritional supplement is released; after 4 hours about 56% of said nutritional supplement is released; after 8 hours about 88% of said nutritional supplement is released; and after 12 hours about 96% of said nutritional supplement is released.

52. (withdrawn) The composition according to claim 1 wherein the timed or retarded release dosage release pellet exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: 90% is released after about 8 hours.

53. (withdrawn) A method of producing a composition of one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement comprising at least one controlled release pellet comprising the steps of: (a) weighing the water-soluble nutritional supplement formulation components, wherein said formulation components comprise a saccharide, an excipient, a lubricant, an agglutinative, a stabilizer and a plasticizer, such that the following proportions are present by weight: the nutritional supplement is about 60% to 95% by weight; the saccharide is about 1.5% to about 15% by weight; the excipient is about 0.6% to about 6% by weight; the lubricant is about 0.07% to about 1% by weight; the agglutinative is about 0.3% to about 3% by weight; Shellac Gum is about 1% to about 10% by weight; and the plasticizer is about 0.1%-1% by weight; (b) preparing a solution with said agglutinative; (c) preparing a mixture with the excipient and half of the lubricant (d) adding said mixture of excipient and lubricant to the saccharide and about one half of said solution of the agglutinative; (e) forming said pellets from the mixture of step (d); (f) drying said pellets; (g) applying the water-soluble nutritional supplement using the remainder of the agglutinative solution to make the pellets; (h) drying the pellets after the application is complete; (i) preparing a solution using the stabilizer,

plasticizer and the other half of the lubricant; (j) applying solution of step (i) to the pellets to form the timed or retarded release pellets; (k) drying the pellets; (l) assaying the pellets and the timed or retarded release pellets in a solution of gastric pH; and (m) adjusting the amounts of said formulations components to attain the desired timed or retarded release.

54. (withdrawn) The method according to claim 49 wherein said composition of one or more said pellets for a timed or retarded release capsule dosage of said water-soluble nutritional supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hours about 10% to about 30% of the nutritional supplement is released; and after 4 hours about 50% to about 75% of said nutritional supplement is released; after 8 hours about 75% to about 95% of said nutritional supplement is released; after 12 hours about 80% to about 100% of said nutritional supplement is released.

55. (withdrawn) The method according to claim 50 wherein said composition of one or more pellets for a timed or retarded release capsule dosage of said water-soluble nutritional

supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hour about 19% of the nutritional supplement is released; after 4 hours about 59% of the nutritional supplement is released; after 8 hours about 81% of the nutritional supplement is released; and after 4 12 hours about 88% of the nutritional supplement is released.

56. (withdrawn) A method of producing a composition of one or more pellets for a timed or retarded release capsule dosage of a water-soluble nutritional supplement comprising at least one controlled release pellet comprising the steps of: (a) weighing the water-soluble nutritional supplement formulation components, wherein said formulation components comprise a saccharide, an excipient, a lubricant, an agglutinative, and a plasticizer, such that the following proportions are present by weight: the nutritional supplement is about 60% to 95% by weight; the saccharide is about 1.5% to about 15% by weight; the excipient is about 0.6% to about 6% by weight; the lubricant is about 0.3% to about 3% by weight; the agglutinative is about 0.3% to about 3% by weight; the plasticizer is about 1.5% to about 12% by weight; (b) preparing a solution with said agglutinative; (c) preparing a mixture with the excipient and half of the

lubricant; (d) adding said mixture of excipient and lubricant to the saccharide and about one half of said solution of the agglutinative; (e) forming said pellets from the mixture of step (d); (f) drying said pellets; (g) applying the water-soluble nutritional supplement using the remainder of the agglutinative solution to make the pellets; (h) drying the pellets after the application is complete; (i) preparing a solution using the plasticizer and the other half of the lubricant; (j) applying solution of step (i) to the pellets to form the timed or retarded release pellets; (k) drying the pellets; (l) assaying the fast release pellets and the timed or retarded release pellets in a solution of gastric pH; and (m) adjusting the amounts of said formulations components to attain the desired timed or retarded release.

57. (withdrawn) The method according to claim 56 wherein said composition of one or more said pellets for a timed or retarded release capsule dosage of said water-soluble nutritional supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree after 1 hour about 15% to about 45% of the nutritional supplement is released: after 1 hour about 15% to about 35% of said nutritional supplement is released; and after

4 hours about 45% to about 75% of said nutritional supplement is released; after 8 hours about 75% to about 95% of said nutritional supplement is released; after 12 hours about 80% to about 100% said nutritional supplement is released.

58. (withdrawn) The method according to claim 57 wherein said composition of one or more pellets for a timed or retarded release capsule dosage of said water-soluble nutritional supplement exhibits the following dissolution profile when tested in a No. 2 (paddle) at 50 rpm in 900 ml of water at 37 degree C+/-0.5 degree: after 1 hour about 30% of the nutritional supplement is released; after 4 hours about 56% of the nutritional supplement is released; after 8 hours about 88% of the nutritional supplement is released; and after 12 hours about 96% of the nutritional supplement is released.

59. (withdrawn) A method of analyzing a composition of one or more pellets for a timed or retarded release capsule dosage of a glucosamine sulfate sodium chloride form comprising at least one controlled release pellet comprising: performing chromatography on said pellets wherein, at least 10 capsules containing pellets are weighed individually and the average weight of their content is determined to be between about 1269.02 to about 1460

mg/capsule; the mean is determined and the relative standard deviation is not more than about 6%, about 20 mg of glucosamine sulfate sodium chloride is weighed and transferred quantitatively to a 25 ml volumetric flask; water is added to complete the volume; the solution is filtered through a 0.45 micron an HVLP membrane and injected three times into a liquid chromatograph; the relative standard deviation is not more than about 2%; about 40 mg of glucosamine sulfate sodium chloride is weighed and transferred to a 50 ml volumetric flask; water is added to complete volume; the solution is filtered through a 0.45 micron HVLP membrane and injected twice into a liquid chromatograph; the relative standard deviation is not more than about 2%; and filtering said pellets wherein the content of a capsule is crushed and transferred quantitatively to a 500 ml volumetric flask; 200 ml of water is added; the solution is placed in an ultrasonic Triturate for about 15 minutes; water is added to complete the volume and mixed well the solution is filtered through a 0.45 micron HVLP membrane and injected once.

60. (withdrawn) A method for treating arthritis in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of glucosamine, its

nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

61. (withdrawn) A method for maintaining healthy bones and joints in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of glucosamine, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

62. (withdrawn) The method according to claim 56 wherein said glucosamine is provided in a dose ranging from about 100 mg to about 2000 mg per day.

63. (withdrawn) The method according to claim 56 wherein said glucosamine is provided in a dose of about 500 mg per day.

64. (withdrawn) A method for treating arthritis in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of chondroitin, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

65. (withdrawn) A method for maintaining healthy bones and joints in a mammal comprising the administration of the composition according to claim 1 wherein said water-soluble nutritional supplement comprises a nutraceutically effective dose of chondroitin, its nutraceutically acceptable salts, ethers, esters, acid, or other derivatives.

66. (withdrawn) The method according to claim 65 wherein said chondroitin is provided in a dose ranging from about 100 mg to about 2000 mg per day.

67. (withdrawn) The method according to claim 66 wherein said glucosamine is provided in a dose of about 500 mg per day.

68. (previously presented) The composition according to claim 23 wherein said water-soluble nutritional supplement comprises glucosamine sulfate, or nutraceutically acceptable salt, ether, ester, acid or derivative thereof.

69. (previously presented) The composition according to claim 23 wherein said water-soluble nutritional supplement comprises chondroitin, or nutraceutically acceptable salt, ether, ester,

Applicant: Romero
Serial No.: 10/910,787
Filed: August 3, 2004

acid or derivative thereof.